

Version: May2011
Contract/Lab: All Laboratories
Species: MICE
Strain: B6C3F1
Length of Study: CHRONIC

Toxicology Data Management System
Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 334
Report Date: 05/04/2011

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
Male							
Battelle Columbus Laboratory	059902806	10/03/02	728	50(1)	37(682)	53.5	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700308	06/25/02	730	50(1)	34(702)	54.2	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500306	04/26/04	729	50(1)	34(694)	54.6	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903204	09/21/04	729	50(1)	37(698)	56.4	Pyrogallol
Female							
Battelle Columbus Laboratory	059902806	10/02/02	727	50(1)	31(692)	60.8	bis(2-Chloroethoxy)methane
Battelle Columbus Laboratory	059700308	06/24/02	729	50(1)	33(693)	60.9	1,2-Dibromo-2,4-dicyanobutane
Southern Research Institute	059500306	04/26/04	731	50(1)	37(709)	64.6	Methyl trans-styryl ketone
Battelle Columbus Laboratory	059903204	09/20/04	729	50(1)	33(675)	69.3	Pyrogallol

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 335
 Report Date: 05/04/2011

		Male			Female		
#All Organs:							
Benign Tumors							
		41/50 (82%)	40/50 (80%)	37/50 (74%)	27/50 (54%)	39/50 (78%)	33/50 (66%)
		42/50 (84%)			34/50 (68%)		
Overall Incidence	Total	160/200 (80%)	Mean 80%	SD 4.32%	Total	133/200 (66.5%)	Mean 66.5% SD 9.85%
.....							
#All Organs:							
Malignant Tumors							
		26/50 (52%)	27/50 (54%)	37/50 (74%)	31/50 (62%)	31/50 (62%)	42/50 (84%)
		33/50 (66%)			34/50 (68%)		
Overall Incidence	Total	123/200 (61.5%)	Mean 61.5%	SD 10.38%	Total	138/200 (69%)	Mean 69% SD 10.39%
.....							
#All Organs:							
Malignant and Benign Tumors							
		48/50 (96%)	45/50 (90%)	49/50 (98%)	44/50 (88%)	46/50 (92%)	48/50 (96%)
		47/50 (94%)			42/50 (84%)		
Overall Incidence	Total	189/200 (94.5%)	Mean 94.5%	SD 3.42%	Total	180/200 (90%)	Mean 90% SD 5.16%
.....							
#All Organs:							
Hemangioma							
		2/50 (4%)	0/50 (0%)	1/50 (2%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)			1/50 (2%)		
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	2/200 (1%)	Mean 1% SD 1.15%
.....							
#All Organs:							
Hemangiosarcoma							
		5/50 (10%)	6/50 (12%)	6/50 (12%)	7/50 (14%)	1/50 (2%)	5/50 (10%)
		5/50 (10%)			6/50 (12%)		
Overall Incidence	Total	22/200 (11%)	Mean 11%	SD 1.15%	Total	19/200 (9.5%)	Mean 9.5% SD 5.26%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 336
 Report Date: 05/04/2011

		Male				Female			
#All Organs:									
Hemangiosarcoma or Hemangioma									
		7/50 (14%)	6/50 (12%)	7/50 (14%)	8/50 (16%)	1/50 (2%)	5/50 (10%)		
		6/50 (12%)			7/50 (14%)				
Overall Incidence	Total	26/200 (13%)	Mean 13%	SD 1.15%	Total	21/200 (10.5%)	Mean 10.5%	SD 6.19%	
.....									
#All Organs:									
Histiocytic Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)	3/50 (6%)	1/50 (2%)	1/50 (2%)		
		1/50 (2%)			0/50 (0%)				
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	
.....									
#All Organs:									
Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type									
		0/50 (0%)	1/50 (2%)	4/50 (8%)	9/50 (18%)	14/50 (28%)	20/50 (40%)		
		2/50 (4%)			13/50 (26%)				
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 3.42%	Total	56/200 (28%)	Mean 28%	SD 9.09%	
.....									
#All Organs:									
Mesothelioma: Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Mesothelioma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 337
 Report Date: 05/04/2011

		Male				Female			
#All Organs:									
Mesothelioma: Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#All Organs:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	
.....									
#All Organs:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	
.....									
*Adrenal Cortex:									
Adenoma									
		6/49 (12%)	6/50 (12%)	6/50 (12%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		9/50 (18%)				1/50 (2%)			
Overall Incidence	Total	27/199 (13.57%)	Mean 13.56%	SD 2.96%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 338
 Report Date: 05/04/2011

		Male				Female			
*Adrenal Cortex:									
Plasma Cell Tumor Malignant									
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Benign									
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
*Adrenal Medulla:									
Pheochromocytoma Malignant									
		0/49 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Adrenal Medulla:									
Pheochromocytoma: Benign, Complex, Malignant, NOS									
		0/49 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
		0/50 (0%)				2/50 (4%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	
.....									
*Bone Marrow:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 339
 Report Date: 05/04/2011

		Male				Female			
*Bone Marrow:									
Hemangiosarcoma									
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	5/200 (2.5%)	Mean 2.5%	SD 2.52%	
.....									
*Bone Marrow:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				3/50 (6%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	
.....									
#Bone:									
Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Bone:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 340
 Report Date: 05/04/2011

		Male				Female			
#Bone:									
Osteosarcoma or Osteoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	
.....									
*Brain:									
Meningioma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Meningioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Meningioma: Benign, Malignant, NOS									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Oligodendroglioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 341
 Report Date: 05/04/2011

		Male				Female			
*Brain:									
Oligodendroglioma, Glioma, or Astrocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Brain:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Clitoral/Preputial Gland:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Clitoral/Preputial Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)	
		0/50 (0%)				0/49 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 342
 Report Date: 05/04/2011

		Male				Female			
*Clitoral/Preputial Gland:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/48 (0%)	
		1/50 (2%)				0/49 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	
.....									
*Clitoral/Preputial Gland:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)	
		1/50 (2%)				0/49 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
#Esophagus:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Eye:									
Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Harderian Gland:									
Adenoma									
		10/50 (20%)	7/50 (14%)	2/50 (4%)		3/50 (6%)	6/50 (12%)	4/50 (8%)	
		6/50 (12%)				1/50 (2%)			
Overall Incidence	Total	25/200 (12.5%)	Mean 12.5%	SD 6.61%	Total	14/200 (7%)	Mean 7%	SD 4.16%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 343
 Report Date: 05/04/2011

		Male				Female			
#Harderian Gland:									
Carcinoma									
		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	2/50 (4%)	0/50 (0%)	
		2/50 (4%)				2/50 (4%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1.91%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
#Harderian Gland:									
Carcinoma or Adenoma									
		12/50 (24%)	7/50 (14%)	3/50 (6%)		3/50 (6%)	8/50 (16%)	4/50 (8%)	
		8/50 (16%)				3/50 (6%)			
Overall Incidence	Total	30/200 (15%)	Mean 15%	SD 7.39%	Total	18/200 (9%)	Mean 9%	SD 4.76%	
.....									
#Harderian Gland:									
Sarcoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Heart:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Large: Cecum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 344
 Report Date: 05/04/2011

		Male				Female			
#Intestine Large: Cecum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Cecum:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Cecum:									
Leiomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Large: Colon/Rectum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 345
 Report Date: 05/04/2011

		Male				Female			
#Intestine Small: Duodenum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Duodenum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Duodenum:									
Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Ileum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Ileum:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 346
 Report Date: 05/04/2011

		Male				Female			
#Intestine Small: Ileum:									
Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Jejunum:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Jejunum:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Jejunum:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 347
 Report Date: 05/04/2011

		Male				Female			
#Intestine Small: Site Unspecified:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Intestine Small: Site Unspecified:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Intestine Small: Site Unspecified:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Intestine Small: Site Unspecified:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Intestine Small: Site Unspecified:									
Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 348
 Report Date: 05/04/2011

		Male				Female			
#Intestine Small: Site Unspecified:									
Polyp Adenomatous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Adenoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
*Islets, Pancreatic:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Islets, Pancreatic:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		2/50 (4%)				1/50 (2%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
*Kidney: Renal Tubule:									
Adenoma									
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.52%	SD 1.04%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 349
 Report Date: 05/04/2011

		Male				Female			
*Kidney: Renal Tubule: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	1/48 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/198 (0.51%)	Mean 0.52%	SD 1.04%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Kidney: Renal Tubule: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Kidney: Renal Tubule: Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 350
 Report Date: 05/04/2011

		Male				Female			
*Kidney: Renal Tubule:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	
.....									
*Liver:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Liver:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hemangiosarcoma									
		1/50 (2%)	1/50 (2%)	4/50 (8%)		2/50 (4%)	1/50 (2%)	1/50 (2%)	
		3/50 (6%)				1/50 (2%)			
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 3%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%	
.....									
*Liver:									
Hepatoblastoma									
		2/50 (4%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		4/50 (8%)				1/50 (2%)			
Overall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 2.52%	Total	2/200 (1%)	Mean 1%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 351
 Report Date: 05/04/2011

		Male			Female		
*Liver:							
Hepatocellular Adenoma							
		33/50 (66%)	35/50 (70%)	31/50 (62%)	22/50 (44%)	31/50 (62%)	30/50 (60%)
		39/50 (78%)			30/50 (60%)		
Overall Incidence	Total	138/200 (69%)	Mean 69%	SD 6.83%	Total	113/200 (56.5%)	Mean 56.5% SD 8.39%
.....							
*Liver:							
Hepatocellular Carcinoma							
		14/50 (28%)	17/50 (34%)	28/50 (56%)	3/50 (6%)	8/50 (16%)	23/50 (46%)
		20/50 (40%)			17/50 (34%)		
Overall Incidence	Total	79/200 (39.5%)	Mean 39.5%	SD 12.04%	Total	51/200 (25.5%)	Mean 25.5% SD 17.92%
.....							
*Liver:							
Hepatocellular Carcinoma or Hepatoblastoma							
		15/50 (30%)	19/50 (38%)	29/50 (58%)	3/50 (6%)	9/50 (18%)	23/50 (46%)
		21/50 (42%)			18/50 (36%)		
Overall Incidence	Total	84/200 (42%)	Mean 42%	SD 11.78%	Total	53/200 (26.5%)	Mean 26.5% SD 17.92%
.....							
*Liver:							
Hepatocellular Carcinoma or Hepatocellular Adenoma							
		40/50 (80%)	41/50 (82%)	45/50 (90%)	22/50 (44%)	32/50 (64%)	38/50 (76%)
		43/50 (86%)			35/50 (70%)		
Overall Incidence	Total	169/200 (84.5%)	Mean 84.5%	SD 4.43%	Total	127/200 (63.5%)	Mean 63.5% SD 13.89%
.....							
*Liver:							
Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma							
		40/50 (80%)	41/50 (82%)	45/50 (90%)	22/50 (44%)	32/50 (64%)	38/50 (76%)
		43/50 (86%)			35/50 (70%)		
Overall Incidence	Total	169/200 (84.5%)	Mean 84.5%	SD 4.43%	Total	127/200 (63.5%)	Mean 63.5% SD 13.89%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 352
 Report Date: 05/04/2011

		Male				Female			
*Liver:									
Hepatocolangiocarcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Hepatocolangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Ito Cell Tumor Benign									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Ito Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Liver:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 353
 Report Date: 05/04/2011

		Male				Female			
*Liver:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Alveolar/Bronchiolar Adenoma									
		6/50 (12%)	10/50 (20%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	1/50 (2%)	
		12/50 (24%)				2/50 (4%)			
Overall Incidence	Total	36/200 (18%)	Mean 18%	SD 5.16%	Total	6/200 (3%)	Mean 3%	SD 1.15%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma									
		5/50 (10%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	3/50 (6%)	3/50 (6%)	
		4/50 (8%)				2/50 (4%)			
Overall Incidence	Total	22/200 (11%)	Mean 11%	SD 2.58%	Total	12/200 (6%)	Mean 6%	SD 1.63%	
.....									
*Lung:									
Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma									
		11/50 (22%)	15/50 (30%)	14/50 (28%)		5/50 (10%)	5/50 (10%)	4/50 (8%)	
		15/50 (30%)				4/50 (8%)			
Overall Incidence	Total	55/200 (27.5%)	Mean 27.5%	SD 3.79%	Total	18/200 (9%)	Mean 9%	SD 1.15%	
.....									
*Lung:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 354
 Report Date: 05/04/2011

		Male				Female			
*Lung:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Lung:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Lung:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 355
 Report Date: 05/04/2011

		Male				Female			
#Lymph Node:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Bronchial:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 356
 Report Date: 05/04/2011

		Male				Female			
#Lymph Node, Mandibular: Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Lymph Node, Mandibular: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mandibular: Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mandibular: Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric: Fibrous Histiocytoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 357
 Report Date: 05/04/2011

		Male				Female			
#Lymph Node, Mesenteric: Hemangioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland: Adenoacanthoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 358
 Report Date: 05/04/2011

		Male				Female			
#Mammary Gland:									
Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
#Mammary Gland:									
Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	4/200 (2%)	Mean 2%	SD 2.31%	
.....									
#Mammary Gland:									
Fibroadenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mammary Gland:									
Fibroma, Fibroadenoma, Carcinoma, or Adenoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	2/50 (4%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	4/200 (2%)	Mean 2%	SD 2.31%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 359
 Report Date: 05/04/2011

		Male				Female			
#Mesentery:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Hemangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Hemangiosarcoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Mesentery:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Nose:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 360
 Report Date: 05/04/2011

		Male				Female			
*Nose:									
Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva):									
Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Oral Mucosa:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Ovary:									
Choriocarcinoma									
						0/50 (0%)	0/50 (0%)	0/49 (0%)	
						0/50 (0%)			
Overall Incidence					Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 361
 Report Date: 05/04/2011

	Male	Female
*Ovary:		
Cystadenocarcinoma		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/49 (0%)
Overall Incidence	Total 0/199 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Cystadenoma		
	2/50 (4%)	3/50 (6%)
	2/50 (4%)	1/49 (2%)
Overall Incidence	Total 8/199 (4.02%)	Mean 4.01% SD 1.62%
.....		
*Ovary:		
Fibrous Histiocytoma		
	0/50 (0%)	1/50 (2%)
	0/50 (0%)	0/49 (0%)
Overall Incidence	Total 1/199 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Granulosa Cell Tumor Benign		
	0/50 (0%)	0/50 (0%)
	1/50 (2%)	0/49 (0%)
Overall Incidence	Total 1/199 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Granulosa Cell Tumor Malignant		
	0/50 (0%)	0/50 (0%)
	0/50 (0%)	0/49 (0%)
Overall Incidence	Total 0/199 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 362
 Report Date: 05/04/2011

	Male	Female
*Ovary:		
Granulosa Cell Tumor: Benign, Malignant, NOS		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total 1/199 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Hemangioma		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total 1/199 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Hemangiosarcoma		
	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total 1/199 (0.5%)	Mean 0.5% SD 1%
.....		
*Ovary:		
Luteoma		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total 0/199 (0%)	Mean 0% SD 0%
.....		
*Ovary:		
Plasma Cell Tumor Malignant		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total 0/199 (0%)	Mean 0% SD 0%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 363
 Report Date: 05/04/2011

		Male				Female			
*Ovary:									
Teratoma Benign									
			0/50 (0%)		0/50 (0%)		0/50 (0%)		0/49 (0%)
			0/50 (0%)						
Overall Incidence		Total	0/199 (0%)		Mean 0%				SD 0%
.....									
*Ovary:									
Teratoma Malignant									
			0/50 (0%)		0/50 (0%)		0/50 (0%)		0/49 (0%)
			0/50 (0%)						
Overall Incidence		Total	0/199 (0%)		Mean 0%				SD 0%
.....									
*Ovary:									
Tubulostromal Adenoma									
			0/50 (0%)		0/50 (0%)		0/50 (0%)		0/49 (0%)
			0/50 (0%)						
Overall Incidence		Total	0/199 (0%)		Mean 0%				SD 0%
.....									
*Pancreas:									
Adenoma									
			0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Pancreas:									
Carcinoma									
			0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 364
 Report Date: 05/04/2011

		Male				Female			
*Pancreas:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		4/49 (8%)	5/50 (10%)	5/47 (11%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	18/196 (9.18%)	Mean 9.2%	SD 1.32%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/47 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%	
.....									
*Pituitary Gland: Pars Distalis or Unspecified Site:									
Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		4/49 (8%)	5/50 (10%)	5/47 (11%)	
		0/50 (0%)				4/50 (8%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	18/196 (9.18%)	Mean 9.2%	SD 1.32%	
.....									
*Pituitary Gland: Pars Intermedia:									
Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/47 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/196 (0.51%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 365
 Report Date: 05/04/2011

		Male				Female			
*Pituitary Gland: Pars Intermedia:									
 Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	0/49 (0%)	0/49 (0%)	1/50 (2%)	0/47 (0%)		
		0/50 (0%)			0/50 (0%)				
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/196 (0.51%)	Mean 0.5%	SD 1%	
.....									
*Prostate:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
*Prostate:									
 Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
*Prostate:									
 Hemangioma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%					
.....									
*Salivary Glands:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 366
 Report Date: 05/04/2011

		Male				Female			
*Salivary Glands:									
 Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Salivary Glands:									
 Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Seminal Vesicle:									
 Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%					
.....									
#Skeletal Muscle:									
 Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
 Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 367
 Report Date: 05/04/2011

		Male				Female			
#Skeletal Muscle:									
Myxosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Rhabdomyosarcoma or Rhabdomyoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skeletal Muscle:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Adenoma or Basosquamous Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 368
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Basal Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 369
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Basosquamous Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	
.....									
#Skin:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Skin:									
Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 370
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Granular Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Hemangiosarcoma									
		1/50 (2%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	2/50 (4%)	2/50 (4%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 1%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Skin:									
Keratoacanthoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 371
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Lipoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Mast Cell Tumor Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Melanoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Melanoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 372
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Myxosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neural Crest Tumor									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Neurofibroma or Schwannoma benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Neurofibrosarcoma or Schwannoma (malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Skin:									
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	5/200 (2.5%)	Mean 2.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 373
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Osteosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Schwannoma Benign									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Skin:									
Schwannoma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 1.63%	
.....									
#Skin:									
Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 374
 Report Date: 05/04/2011

		Male				Female			
#Skin:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma or Papilloma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin:									
Trichoepithelioma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 375
 Report Date: 05/04/2011

		Male				Female			
#Skin: Sebaceous Gland: Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Skin: Sebaceous Gland: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Spinal Cord: Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Spinal Cord: Meningioma Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 376
 Report Date: 05/04/2011

		Male				Female			
*Spleen:									
Fibrous Histiocytoma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
*Spleen:									
Hemangioma									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Hemangiosarcoma									
		3/50 (6%)	1/50 (2%)	3/48 (6%)		5/50 (10%)	0/50 (0%)	2/49 (4%)	
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	8/198 (4.04%)	Mean 4.06%	SD 2.38%	Total	8/199 (4.02%)	Mean 4.02%	SD 4.32%	
.....									
*Spleen:									
Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Spleen:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 377
 Report Date: 05/04/2011

		Male				Female			
#Stomach, Forestomach:									
Mast Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%	Total	4/200 (2%)	Mean 2%	SD 0%	
.....									
#Stomach, Forestomach:									
Squamous Cell Papilloma									
		0/50 (0%)	0/50 (0%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)				1/50 (2%)			
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	4/200 (2%)	Mean 2%	SD 0%	
.....									
#Stomach, Glandular:									
Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 378
 Report Date: 05/04/2011

		Male				Female			
#Stomach, Glandular:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Testes:									
Adenoma									
		2/50 (4%)	2/50 (4%)	0/50 (0%)					
		0/50 (0%)							
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%					
.....									
*Thymus:									
Thymoma Benign									
		0/49 (0%)	0/47 (0%)	0/44 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	0/188 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%	
.....									
*Thymus:									
Thymoma Malignant									
		0/49 (0%)	1/47 (2%)	0/44 (0%)		0/50 (0%)	1/47 (2%)	0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	1/188 (0.53%)	Mean 0.53%	SD 1.06%	Total	1/197 (0.51%)	Mean 0.53%	SD 1.06%	
.....									
*Thymus:									
Thymoma: Benign, Malignant, NOS									
		0/49 (0%)	1/47 (2%)	0/44 (0%)		0/50 (0%)	1/47 (2%)	0/50 (0%)	
		0/48 (0%)				0/50 (0%)			
Overall Incidence	Total	1/188 (0.53%)	Mean 0.53%	SD 1.06%	Total	1/197 (0.51%)	Mean 0.53%	SD 1.06%	

#: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 379
 Report Date: 05/04/2011

		Male				Female			
*Thyroid Gland: C-Cell: Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: C-Cell: Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: Follicular Cell: Adenoma									
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	
.....									
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma									
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/49 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 380
 Report Date: 05/04/2011

		Male				Female			
#Tissue NOS:									
Fibrosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tissue NOS:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				1/50 (2%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Tissue NOS:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tissue NOS:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Tongue:									
Fibroma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 381
 Report Date: 05/04/2011

		Male				Female			
#Tongue:									
Squamous Cell Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tongue:									
Squamous Cell Carcinoma or Papilloma Squamous									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Tooth:									
Odontoma									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		1/50 (2%)				0/50 (0%)			
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Hemangiosarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	
.....									
*Urinary Bladder:									
Plasma Cell Tumor Malignant									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 382
 Report Date: 05/04/2011

		Male				Female			
*Urinary Bladder:									
Sarcoma									
		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/49 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Uterus:									
Adenoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Uterus:									
Carcinoma									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
						1/50 (2%)			
Overall Incidence	Total				Total	2/200 (1%)	Mean 1%	SD 1.15%	
.....									
#Uterus:									
Hemangiosarcoma									
						0/50 (0%)	0/50 (0%)	1/50 (2%)	
						0/50 (0%)			
Overall Incidence	Total				Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
.....									
#Uterus:									
Leiomyoma									
						0/50 (0%)	0/50 (0%)	0/50 (0%)	
						0/50 (0%)			
Overall Incidence	Total				Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
Route: SKIN
Vehicle: ETHANOL

Page: 383
 Report Date: 05/04/2011

	Male	Female
#Uterus: Leiomyosarcoma		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
#Uterus: Polyp Stromal		
	0/50 (0%) 3/50 (6%)	1/50 (2%) 1/50 (2%)
Overall Incidence	Total 5/200 (2.5%)	Mean 2.5% SD 2.52%
#Uterus: Sarcoma		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
#Uterus: Sarcoma Stromal		
	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total 0/200 (0%)	Mean 0% SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		
	0/50 (0%) 3/50 (6%)	1/50 (2%) 1/50 (2%)
Overall Incidence	Total 5/200 (2.5%)	Mean 2.5% SD 2.52%

*: Denominator is number of animals with tissues examined microscopically
 #: Denominator is number of animals necropsied

Version: May2011
 Contract/Lab: All Laboratories
 Species: MICE
 Strain: B6C3F1
 Length of Study: CHRONIC

Toxicology Data Management System
 Tumor Incidence for Selected Control Animal Groups
 Route: SKIN
 Vehicle: ETHANOL

Page: 384
 Report Date: 05/04/2011

		Male				Female			
#Uterus:									
Schwannoma Malignant									
			0/50 (0%)		0/50 (0%)		0/50 (0%)		
			0/50 (0%)						
Overall Incidence		Total	0/200 (0%)		Mean 0%		SD 0%		
.....									
#Vagina:									
Liposarcoma									
			0/50 (0%)		0/50 (0%)		1/50 (2%)		
			0/50 (0%)						
Overall Incidence		Total	1/200 (0.5%)		Mean 0.5%		SD 1%		
.....									
#Vagina:									
Squamous Cell Papilloma									
			0/50 (0%)		0/50 (0%)		0/50 (0%)		
			0/50 (0%)						
Overall Incidence		Total	0/200 (0%)		Mean 0%		SD 0%		
.....									
#Zymbal's Gland:									
Carcinoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	
.....									
#Zymbal's Gland:									
Carcinoma or Adenoma									
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)				0/50 (0%)			
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied